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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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03/26/2004

Jean-Marc Beraud

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EXAMINER

EREZO, DARWIN P

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/809,799	Applicant(s) BERAUD, JEAN-MARC	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-20 and 22-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20 and 22-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/30/09 has been entered.

Claim Objections

2. Claim 17 is objected to because of the following informalities:
3. Claim 17 uses the following terminology to refer to the same structure: "elongated flexible body", "the body", "the elongated body". The applicant is required to correct the claims to use a single term in order to keep the language of the claims consistent. The applicant is also suggested to check the remaining dependent claims for the same issue. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 17-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,899,909 to Claren et al. in view of US 2002/0156489 to Gellman et al.

(claim 17) Claren discloses a device for placing a reinforcing tape in a tissue of the human body, comprising an introducer including: an elongated flexible body 314 extending along a longitudinal axis and having two ends (see Fig. 17) and provided with a lumen for receiving a reinforcing tape 26 (see Fig. 14), said ends having pulling means comprising semi-rigid needles 21A,21B that are integral with the flexible body; and a means for cutting the flexible body into two portions (via dot-and-dash line 37).

Claren is silent with regards to the means for cutting comprising at least one aperture provided in the flexible body into the cavity and extending transversally to the longitudinal axis, the aperture affecting more than half of the circumference of the walls of the cavity, so as to leave only a connecting wall between portions of the flexible body delimited by the aperture, the aperture being capable for allowing passage of a cutting tool between the tape received in the cavity and the connecting wall.

However, Gellman discloses that it is known in the art to provide the flexible body/sheath with at least one aperture extending transversally to the longitudinal axis

(see Fig. 8I for the aperture), the aperture affecting more than half of the circumference of the walls of the cavity so as to leave only a connecting wall (defined by sections 150A and 160A) between portions of the flexible body delimited by the aperture, the aperture being capable for allowing passage of a cutting tool between the tape received in the cavity and the connecting wall.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the dot-and-dash line of Claren with the structure disclosed by Gellman because the means taught by Gellman not only allows the flexible body to be separated into two portions, but the bottom sections 150b, 160b also allows a surgeon to align the middle portion of the sling against the patient's urethra.

(claim 18) The aperture disclosed by Gellman is constructed and arranged to allow placement of the tape in the cavity.

(claim 19) The cutting means disclosed by Gellman comprises at least two apertures positioned facing each other (see Fig. 8I, the envelope has two apertures on either side of the top sections 150A and 160A).

(claim 20) Claren is also silent with regards to the walls having a series of perforations for sterilization. However, Gellman discloses in Fig. 3A-3B an elongated body having apertures/perforations along its length. The apertures are used to delivery drug into the tissues (paragraph [0144]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the device of Claren to include the apertures as it would allow the device to delivery drugs to the tissues. The apertures would also be capable of allowing sterilization of the device.

(claim 22) The device of Claren comprises a tape 26 freely positioned inside the cavity, and wherein the aperture disclosed by Gellman would allow placement of the tape in the cavity (once the bottom sections 150b, 160b are separated).

7. Claims 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claren et al. in view of Gellman et al. ('489) and in further view of US 6,423,080 to Gellman et al. ('080).

(claims 23 and 24) The modified device of Claren discloses all the limitations of the claims except for the device further comprising a perforator guide or trocar.

However, Gellman ('080) discloses that is well known in the art to use a perforator guide 1410 having a first end 1414 arranged for introduction into the body of a patient and an opposite end provided with a handle 1412 (see Figs. 66-79), wherein the first portion has an arcuate shape in a plane (see Fig. 66).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Claren to use the perforator guide of Gellman ('080) since it would allow the surgeon to remotely install the sling into the patient. It also allows provide better control of the deployment of the sling.

(claim 25) The modified device of Claren in view of Gellman ('080) discloses all the limitations of the claims except for the arcuate portion of the perforator guide extends over an angular sector larger than 140'. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the recited angle since it has been held that discovering an optimum value of a result

effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

(claims 26-28) The modified device of Claren in view of Gellman ('080) discloses all the limitations of the claims except for the arcuate portion of the perforator guide extends over an angular sector between 150° and 170"; the arcuate portion of the perforator guide has a radius of curvature between 30 and 60 mm for a portion of the perforator guide extending between the handle and the first end, wherein the radius of curvature is between 40 and 50 mm. However, it would have been obvious one to one of ordinary skill in the art to arrive at the recited ranges since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

(claims 29-32) The modified device of Claren in view of Gellman ('080) discloses all the limitations of the claims except for the perforator guide having a helicoidal shape at the first end, wherein the shape is a portion of a helicoidal coil extending over an angle between 180° and 360°, wherein the shape is a portion of a helicoidal coil extending over an angle between 255° and 270°, wherein the coil of the perforator guide has a radius of curvature between 20 mm and 40 mm with a pitch between 15 mm and 25 mm. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the shape of Gellman to have a helicoidal shape since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). It also

would have been obvious to arrive at the recited ranges since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

8. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claren et al. in view of Gellman et al. ('489) and Gellman et al. ('080), and in further view of US 2002/0055748 to Gellman et al ('748).

The device of Claren, as mainly modified by Gellman ('080) discloses all the limitations of the claims except for the use of a removable tubular sleeve with a complementary shape to that of the perforator guide, constructed and arranged for engagement onto the perforator guide and to remain in the body of the patient after removing the perforator guide, so as to define a tunnel for the passage of pulling means of the introducer, wherein the tubular sleeve has a length greater than a useful length of the perforator guide and comprises a side aperture for placement of the perforator guide, the side aperture being located at a distance from a free end of the sleeve less than or equal to the useful length of the perforator guide.

However, Gellman ('748) discloses such a removable tubular sleeve that remains in the body of the patient so as to define a tunnel for the passage of the introducer (see Fig. 13). Therefore, it would have been obvious to one of ordinary skill in the art to further modify the system of Claren to include a removable tubular sleeve as taught by the '748 reference since it would allow for an easier deployment of the introducer into the cavity of the human body.

Response to Arguments

9. Applicant's arguments with respect to claims 17-20 and 22-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezzo/
Primary Examiner, Art Unit 3773

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